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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/505,317	08/20/2004	Tina Rademacher	RO0861US(#90568)	5171

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D Peter Hochberg
6th Floor
1940 E 6th Street
Cleveland, OH 44114-2294

EXAMINER	
TRAN, SUSAN T	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/505,317	RADEMACHER ET AL.	
	Examiner	Art Unit	
	S. Tran	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 27-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 27-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed 01/30/08 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is: the gas-forming agent *not combined with an acid*.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-21 and 27-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

It appears that the present specification does not provide support for the limitation "carbon dioxide forming substance which is not combined with an acid".

While the present specification discloses that the preparation is capable of disintegrating slowly within a period of 3-15 minutes, it appears that the present

specification does not provide support for the limitations "preparation is not capable of disintegrating in an aqueous medium", and "removing the preparation from said oral mucosa after the active substance has been released" in claim 43. Slowly disintegrates is not the same as no capable of disintegrate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 43 is rejected for failing to further limit the subject matter of claim 42. While claim 42 requires the preparation to disintegrate upon contact with oral mucosa, claim 43 recites that the preparation is not capable of disintegrate. Applicant is required to cancel the claim, or amend the claim to place it in proper dependent form, or rewrite the claim in independent form.

Claim 43 is also rejected in the use of the phrase "preparation is not capable of disintegrating in an aqueous medium". Does this mean that the preparation will not disintegrate at all in the aqueous medium?

Claim Rejections - 35 USC § 102

Claims 1, 2, 5-12, 16, 17, 20, 21, 29-31, 35, 36 and 39-41 are rejected under 35 U.S.C. 102(a) as being anticipated by Falkenhausen et al. WO 02/02085 A2 (using US Publication 2004/0028732).

Falkenhausen teaches a rapidly disintegrating sheet or wafer dosage form having thickness of between 0.1-5 mm, the dosage form comprising matrix-forming

polymers, active ingredients, and a carbon dioxide gas forming agent (paragraphs 0006, 0036 and claim 11). Polymers include cellulosic polymers, and water-soluble polysaccharide (abstract; paragraphs 0017-0020). The dosage form further comprises eucalyptus oil, peppermint oil, flavor, sweetener, other additives, and foams such as propylene glycol (paragraphs 0023-0030). The dosage form disintegrates in the oral cavity in the range from 10-30 second (paragraph 0009).

Claims 1-3, 5-12, 15-21, 29-31 and 33-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Ziegler et al. US 2006/0057207 A1.

Ziegler discloses a fast disintegrating film or wafer comprising: an active agent, film-forming polymers, effervescent disintegrant (gas-forming agent), and filler (paragraph 0074). Film-forming polymers are disclosed in paragraph 0076. The film-forming polymers are added in an amount that falls within the claimed range, *e.g.*, 0.01-99% (paragraph 0076). Effervescent disintegrant includes sodium carbonate (paragraph 0048). The film further comprises water, additional film-forming agent, plasticizing agent, flavoring, saliva stimulating agents, cooling agent, surfactant, stabilizing agent, emulsifying agent, thickening agents, binding agent, coloring agent, sweetening agent, fragrance, and the like (paragraphs 0077-0088). Ziegler further discloses the film has a thickness that falls within the claimed range, *e.g.*, 30 μm to 300 μm (paragraph 0074). Ziegler also discloses the film disintegrates in a patient's oral cavity in less than one minute (paragraph 0009).

It is noted that Ziegler does not explicitly teach the claimed properties such as the density. However, the density is inherent because Ziegler teaches the use of the same polymer, and the same carbon dioxide forming agent to obtain the same wafer composition having the claimed disintegrating time.

Claim Rejections - 35 USC § 103

Claims 1-12, 15-21, 27-31 and 33-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al. US 2006/0057207, in view of Pather et al. US 2003/0091629.

Ziegler is relied upon for the reason stated above. Ziegler does not specifically teach the claimed amount of the gas-forming agent. However, Ziegler teaches the use of saliva stimulating agent in an amount that falls within the claimed range, *e.g.,* about 0.01% to about 12% (paragraphs 0061 and 0078). Most importantly, Ziegler discloses the use of sodium carbonate as an effervescent disintegration agent to stimulate saliva production, thereby providing additional water to aid in further effervescence and disintegration (paragraph 0046). To be more specific, Pather teaches an effervescing sublingual buccal dosage form comprising a drug, an additive, and an effervescent in an amount of about 5% to about 95% (abstract; and paragraph 0014). Pather further teaches effervescent includes sodium carbonate, and potassium carbonate (paragraph 0015).

Thus, it would have been obvious to one of ordinary skill in the art to modify the fast disintegrating dosage of Ziegler to include the carbonates in an amount in view of

the teaching of Pather to obtain the claimed invention. This is because Pather teaches the use of effervescent in such an amount to influence the permeability of the medicament across the buccal, sublingual, and gingival mucosa (paragraphs 0008 and 0009), because Ziegler teaches the use of sodium carbonate in the dosage form, and because Ziegler teaches the desirability to obtain a fast disintegrating dosage form useful for buccal and sublingual delivery.

Claims 1-12, 16, 17, 19-21, 27-31, 35, 36 and 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Falkenhausen et al. WO 02/02085 A2 (using US Publication 2004/0028732), in view of Pather et al. US 2003/0091629.

Falkenhausen is relied upon for the reason disclosed in the 102(a) rejection. Falkenhausen does not explicitly teach the claimed carbon dioxide forming substance.

Pather teaches an effervescing sublingual buccal dosage form comprising a drug, an additive, and an effervescent in an amount of about 5% to about 95% (abstract; and paragraph 0014). Pather further teaches effervescent includes sodium carbonate, and potassium carbonate (paragraph 0015).

Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage of Falkenhausen to include the carbon dioxide forming substance such as sodium carbonate in an amount in view of the teaching of Pather to obtain the claimed invention. This is because Pather teaches the use of effervescent in such an amount to influence the permeability of the medicament across the buccal, sublingual, and gingival mucosa (paragraphs 0008 and 0009), because Pather teaches the use of sodium carbonate to evolve gas such as carbon dioxide gas (paragraphs

0015-0016), and because Falkenhausen teaches the desirability of using carbon dioxide gas forming substance.

Falkenhausen further does not teach the amount of water-soluble polymer. However, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. When the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). The examiner is unable to determine any unexpected result over the claimed amount of polymer because Falkenhausen teaches the use of the same matrix-forming polymer to obtain a rapidly disintegrating film that has the same disintegration time, *i.e.*, 10-30 second (ID). Thus, it would have been obvious to one of ordinary skill in the art to, by routine experimentation select an amount of matrix-forming polymer that falls within the claimed range, because Falkenhausen the desirability to use the same matrix-forming polymer to obtain the same film shape dosage form having the same disintegrating time.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al. or Falkenhausen et al., in view of Myers et al. US 2007/0122455.

Ziegler and Falkenhausen are relied upon for the reasons stated above. The references do not teach ethyl cellulose as firm-forming polymer.

Myers teaches a uniform film for rapid-dissolve dosage form comprising ethyl cellulose as a matrix-forming polymer (paragraph 0063).

Thus, it would have been obvious to one of ordinary skill in the art to modify the rapidly disintegrating dosage of Ziegler or Falkenhausen using ethyl cellulose as a film-forming polymer in view of the teaching of Myers, this is because Myers teaches using ethyl cellulose in rapid-dissolve film-shaped dosage form is well known in the art, and this is because Ziegler and Falkenhausen teach the desirability for using cellulosic film-forming polymers.

Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ziegler et al., in view of Tapolsky et al. US 5,800,832.

Ziegler is relied upon for the reasons stated above. The reference does not expressly teach the film layers as claimed in claims 13 and 14.

Tapolsky teaches a water-soluble, bioerodable delivery device comprising an adhesive layer and a non-adhesive backing layer (abstract). The two layers have different dissolution rate (permeability) (column 5, lines 34-36). Thus, it would have been obvious to one of ordinary skill in the art to modify the delivery thin film of Ziegler to contain the mucoadhesive bioerodable film in view of the teaching of Tapolsky, because Tapolsky teaches a mucoadhesive bioerodable film provides adhesive to mucosal surface with minimal discomfort and ease of use (column 4, lines 47-50), because Tapolsky teaches using mucoadhesive to maintain the delivery device at the site of treatment (column 1, lines 13-21), and because Ziegler teaches the thin film delivery system includes multi-layer system (paragraph 0074).

Response to Arguments

Applicant's arguments filed 01/30/08 have been fully considered but they are not persuasive.

Applicant indicates that support for the limitation "not combined with an acid" may be found at page 5, last paragraph, of the original application as filed in the corresponding PCT application which states "Combined with an acid, but also without an acid ..." and in the amended page 5 of the corresponding PCT which had been amended during the international phase, which states "...carbon dioxide-forming substance without added acid ..." In this regard, it is noted that the latter phrase was inadvertently excluded from the text of the substitute specification as filed, and therefore the current amended to paragraph [000017] simply places said paragraph in agreement with amended page 5 of the corresponding PCT application. It is further noted that the English translation of the page 5 amendment erroneously translated the German term for "acid" as "salt" but that "acid" is the correct term therein.

However, it is noted that the submitted PCT application is not in English. Therefore, the examiner is unable to find support for newly added limitation.

The obviousness double patenting rejection over copending application 10/468230 has been withdrawn in view of applicant's arguments.

The terminal disclaimer filed on 01/30/08 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of copending application 10/517093 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Applicants argues that the present invention as defined in the presently amended claims 1 is patentably distinct from the inventions disclosed in both Falkenhausen, et al. and Ziegler, et al. In particular, the Applicants submit that while Falkenhausen, et al. generally teach sheet-like dosage forms that may contain carbon dioxide-forming substances, the reference fails to disclose preparations which comprise at least one carbon dioxide-forming substance which is not combined with an acid (emphasis added), as set forth in present claim 1, as amended herein.

However, it is noted that Falkenhausen teaches the use of acid as a possibility incase the active agent is insoluble or unstable under basic condition (paragraph 0029). Accordingly, the addition of acid may not be necessary. Note the process recited in the claims of Falkenhausen does not require the addition of the acid.

Applicant argues that while Zeigler, et al., in the '207 application, mentions effervescent disintegrants, the reference fails to disclose any dosage form that contain carbon dioxide-forming compound that is not combined with an acid, as recited in present claim 1.

However, applicant has not pointed out where Zeigler requires that the carbon dioxide-forming compound be combined with an acid. Paragraph 0048 teaches the use of effervescent disintegration agent includes those that evolve gas.

Applicants argues that the above 103(a) rejections should be withdrawn because the cited references only teach the use of alkali metal carbonate solely for the effervescent purposes. It is submitted that none of the cited references teach or

otherwise suggest a taste-masking effect that may be caused by incorporating carbon dioxide-forming substances.

However, in response to applicant's argument, it is noted that the limitation "for reducing or completely suppressing an unpleasant taste sensation caused by said at least one active substance" recited in the present claims is a future intended use feature. If a prior art structure is capable of performing the intended use as recited in the preamble, then it meets the claim. See, e.g., *In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). In the present cases, it is noted that the cited references teach the use of carbon dioxide-forming compound in the same dosage form suitable for the same purpose, namely, a film or wafer pharmaceutical preparation suitable for administration in the oral cavity. Ziegler teaches the desirability of pleasant mouth feel, taste-masking dosage form throughout the disclosure (see for example paragraphs 0047, 0064 and 0090; and claims 16 and 17). Falkenhausen teaches the dosage form having improved organoleptic properties (paragraph 0028). Accordingly, the rejections are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1618